

Amendments to the Specification:

Please replace the paragraph beginning on page 7, line 25 with the following amended paragraph:

Specifically, this invention addresses outstanding problems by providing: a) an improved tamper evident end cap assembly including a captivated luer lock syringe cap for closing the discharge port in the nozzle of a loaded syringe, b) an improved sterile package with the end cap assembly encapsulated within it, for transport to, and, prior to use, for storage at a medical facility; and c) an improved combination of a drug loaded syringe and tamper evident end cap assembly for use in dosing a patient. The end cap assembly is especially adapted to mate with and be used with what is referred to herein as a standard syringe, one which is a "carbon copy" of the type used at a given medical facility where it is drug loaded and delivered to a nurse's station for injecting a patient with the dose. Any unauthorized access to the loaded drug contents, once the syringe has been loaded and closed prior to its ultimate use, requires removal of the syringe cap by an unauthorized person[[,]]. ~~and the~~ The fact that such a removal occurred is clearly evident, if it does in fact happen.

Please replace the paragraph beginning on page 8, line 19 with the following amended paragraph:

Generally, in a first form, this invention provides an improved tamper evident end cap assembly including a captivated luer lock syringe cap for closing the discharge port on the nozzle of a drug loaded syringe. In another form, the invention provides a combination composed of a) the improved end cap assembly and b) a sterile package to keep the end cap, or a plurality of such end cap assemblies, sterile during a period of storage at a manufacturing site, during transport ~~of it~~ to a medical facility, and during storage, ~~there~~ until ready for use such as by capping a drug loaded syringe. In yet another form, the invention is of an improved tamper evident end cap assembly mounted on a drug loaded syringe for the "last mile" delivery to a nurses'[[s]] station ready for use by dosing a patient by injection.

Please replace the paragraph beginning on page 9 line 17 with the following amended paragraph:

Another problem is that syringe drug doses are often wasted. In medical practice a doctor often writes orders directing that "up to" a certain amount of a drug, which defines a limit which can be safely tolerated by a patient[[,]] and which may be administered[[,]]if requested by the patient or circumstances justify it. This often results in drug doses being loaded into many syringes which doses are not actually administrated. These

drug doses can be routinely recycled provided if there is an assurance that the drug has not been contaminated and the syringe can be opened without comprising the drug. This invention provides structure which accommodates that purpose.

Please replace the paragraph beginning on page 18, line 10 with the following amended paragraph:

The tamper evident end cap assembly 10 is composed of two chief structural elements: a generally cup or sleeve shaped end cap member 13 which forms a shield, and the syringe cap 14 loosely captivated within the end cap member 13. Importantly, the end cap member 13 further includes an end wall piece or floor piece 18 comprising means to captivate the syringe cap 14 within the end cap member 13, constraining it such that generally only a rotational and limited axial movement occurs between the septum surface 54 and the end wall or floor piece 18. Simply put, the syringe cap 14 is free to rotate in the end cap member 13 but it is captivated loosely, as opposed to tightly within the end cap member 13; and it is constrained to only limited axial movement of a predetermined distance in one axial direction only. To this purpose, the inner end face of the floor piece 18 is configured to form a pattern in relief comprising the aforementioned second, one way drive structure 58', which is sized and configured to mate with the first

mentioned pattern in relief comprising the first drive structure 58 and which is a mirror image of the pattern in relief of the first drive structure 58 formed on the septum face 54 in the syringe cap 14. These components engage one another upon assembly and comprise a one way drive assembly 58 and 58' for installing the combined assembly 17 of Figure 11 on a syringe nozzle 2. In other words the floor piece 18, specifically its inner end surface when disposed in the cup shaped member 13, and the captivated syringe cap 14, specifically its septum surface 54 within the skirt 52, confront one another, engage and comprise a one way drive assembly 58 and 58' to axially displace the syringe a predetermined axial distance on relative rotation of these two pieces for installing of the end cap assembly 10, as a whole, on a drug loaded syringe. This one way drive assembly is structured to engage and drive the confronting first and second drive structures 58 and 58' ~~are seen~~ as best indicated in the assembled combination 17, including the end cap assembly 10 of Figure 11.

Please replace the paragraph beginning on page 25, line 13 with the following amended paragraph:

The end cap assembly 10 may be color coded, for example red may indicate morphine and a different color might indicate a different drug. An end cap assembly 10 according to the invention

may be packaged in a non porous plastic tray or blister pack with an out turned open lip surface formed about an open mouth, which is spanned by a lid composed of sheet material which is peelable. The material of the lid is preferably Tyvek, a sterile packaging of spunbonded olefin manufactured from very fine filaments of high-density polyethylene bonded together by heat and pressure. Tyvek is the trademark of the material; and it is made by the E. I. DuPont Company of Wilmington, Delaware or one of its subsidiaries. It permits sterilization by a gas under pressure and release of the gas; but it prohibits passage of micro organisms into the package and therefore maintains the end cap assembly in the tray in a sterile condition prior to use. An individual assembly is preferred in each tray or blister with a separate lid associated with each tray or pack. This is because the sterility of all of a plurality of end cap assemblies in the same tray or package may become contaminated and compromised when the [[a]] tray lid is removed exposing all within the tray to ambient conditions. In a preferred embodiment the assemblies may be in a row of trays joined ~~together~~ together in a strip with cross perforations so that individual packets may be severed from the strip. Preferably the lids are provided with a tab to initiate peeling to expose an assembly, especially when only one of a particular color code is required at a time.